

## DEPARTMENT OF RESEARCH PROGRAMS



Walter Reed National Military Medical Center

# Military Medical Research News

Vol. 4, Issue 6 • June 2017

# Science is the winner as researchers vie for awards Department hosts annual Ashford, Phillips competitions

### by Paula Amann

When is it safe to drive after hip surgery? What drugs might limit unwanted bone growth after amputation? And does a new antibody born in a local laboratory hold promise for ovarian and gastrointestinal cancer?

These are a few of the research questions probed during last month's competitions for the Bailey K. Ashford and Robert A. Phillips Awards during the Research Symposia at Walter Reed National Military Medical Center.

The May 9-10 Symposia were part of Research and Innovation Month, which drew 180 abstracts for both pure research and other projects ranging



PATIENT ADVOCATE – Claudia Avila, wife of Army Capt. Luis Avila, who was severely injured in Afghanistan, shares her story at the Paul Florentino Patient- and Family-Centered Awards on May 4. See article on page 7. (Photo by Paula Amann)

from quality improvement to patientand family-centered care. (See related stories on pages 4-12.)

At the awards ceremony on May 10, Navy Capt. John Rotruck, the hospital's chief of staff, presented certificates to all the winners. The laboratory Ashford prize went to Army Capt. Gabriel Pavey, and the clinical prize went to Navy Lt. Cmdr. George C. Balazs.

Garnering this year's Phillips awards were Capt. Christopher Daniels (resident laboratory category), Lt. Luke Johnston (resident clinical), Maj. Kristen Zeligs (fellow/staff laboratory), and Lt. Col. E. Matthew Ritter (fellow/staff clinical).

The quartet of Phillips winners went



Army Capt. Gabriel J. Pavey won a Bailey K. Ashford Award for a study of new drugs that could help reduce heterotopic ossification, unwanted bone formation that often follows blast trauma. Here he presents his work at Research Symposium I on May 9. (Photo by John Fadoju)

on to compete in the Navy-wide Academic Research Competition, where all earned awards. Ritter won the first-place clinical award for staff; Johnston won second place for trainees. In the Basic Science category, Daniels won first place for trainees; Zeligs won second place for staff. Meanwhile, Johnston pocketed the special award for health, and Zeligs took home the one for partnerships.

In remarks before the earlier awards ceremony at on May 10, Navy Cmdr. Robert Liotta signaled the importance of all the research competitions.

"Research truly saves lives," said Liotta, the new director of Education, Training and Research at Walter Reed Bethesda. "We often complain that the pace of science seems excruciatingly slow, but in the past 10 years, great strides have been made."

See SCIENCE, page 13



### DEPARTMENT OF RESEARCH PROGRAMS



Army Col. Peter Weina, chief of Department of Research Programs (official photo)

The Department of Research Programs (DRP) at Walter Reed National Military Medical Center supports research in the National Capital Region (NCR).

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other NCR programs.

MILITARY MEDICAL RESEARCH NEWS

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This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). Please send any timely information by the 15th day of the prior month for the following month's issue. Send your ideas, pictures or infographics to paula.m.amann.ctr@mail.mil.

Not on our email list? Don't miss an issue! Please drop us an email, and we will add you to our distribution list.

### RESEARCH FIRST STEPS

Our protocol navigators are available to help you start the process and assist you with your submission. To make an appointment with a protocol navigator, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, on the third floor, to the left of the elevators.

### RESEARCH ROUNDTABLE SCHEDULE

Walter Reed National Military Medical Center America Building (Building 19), Second floor, Room 2301

- Tuesday, July 18, 1200-1300
- Tuesday, August 22, 1200-1300

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# **EIRB TIP OF THE MONTH**Tailoring your templates for

multisite projects

For a multisite project, the lead site should upload a template for the Master or Core Consent form in the initial submission, as needed. The template should not be specific to a particular PI or institution, since more than one principal investigator and institution will be using it.

Each performance site should tailor the template to its institution and participants. If one performance site is doing different procedures than another site, their consent forms should be different.

If a modification is being made that will affect all sites and their consent forms, consider revising the template and the consent form for each performance site. If the modification affects a single site's consent form, the template does not need to be revised.

Please upload a clean version of the latest approved consent template with the continuing review for the lead site. Each performance site should upload a copy of its latest approved consent form then, as well.

Make sure to remove track changes or editing marks on the consent form before uploading. Otherwise, edits will appear in the stamped version. Thanks for your attention to detail!



### **ANNOUNCEMENTS**

### **Webinars to present Common Rule updates**

The Common Rule is changing. In response, the Department of Research Programs is hosting a series of webinars on Thursday afternoons throughout the month of June. See back cover for schedule and topics.

### Clinical trials for medical devices get new oversight options

New regulations based on the 21st Century Cures Act, which became law on December 13, 2016, are revamping the oversight of clinical trials. The act amends the Food, Drug, and Cosmetic Act by removing the requirement for local Institutional Review Board (IRB) review for Investigational Device Exemption (IDE) studies and for the use of Humanitarian Device Exemption (HDE) devices by striking the references to the term "local."

The new language means that medical device investigators, sponsors and clinical sites can choose to rely on a central IRB rather than an institution's local IRB for these activities. This includes IRB review for multisite studies.

Learn more about a June 7 rule on the new law at <a href="https://www.federalregister.gov/documents/2017/06/07/2017-11816/">https://www.federalregister.gov/documents/2017/06/07/2017-11816/</a> <a href="https://www.federalregister.gov/documents/2017/06/">https://www.federalregister.gov/documents/2017/06/</a> <a href=

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- Estimating reliability between raters
- Odds ratios and relative risks
- Regression analysis
- Principal component analysis and factor analysis
- Introduction to Statistical Package for Social Sciences (SPSS)
- Analyzing with Excel (including pivot tables, row and column calculations, and graphing)
- ➤ New this year: Introduction to R (a statistical programming language)

Got questions? Suggestions? Ready to schedule a class?

Contact Mr. Francois Tuamokumo at francois.tuamokumo.civ@mail.mil



# Poster Week winners spur fresh medical practice Inquiry competitors explore, enhance care across the hospital

### by Paula Amann

If vying for quality improvement awards is a leading indicator, this year's more than threefold surge in the number of such projects augurs an upswing for Walter Reed National Medical Military Center. Between 2016 and 2017, the number of QI abstracts in the Poster Week Competition jumped from 8 to 27.

The half-day event on May 9 was part of Research and Innovation Month, held each May at the hospital. On the following day, 10 finalists competed for the Paul Florentino Patient- and Family-Centered Care Award. (See story on page 7.)

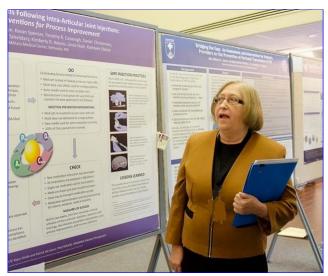
The non-research categories also included evidence-based practice, up to 5 projects this year from 2 projects last year, and case reports, down from last year's total of 86 to 67 this year. Top winners of all the non-research poster categories gave slide presentations at Research Symposium I on May 9.

Such was the caliber of the swelling number of quality improvement projects that Navy Cmdr. William Danchanko, who coordinated judging for this year's competition, opted to give three awards – rather than the usual one – in this category.

"The quality, not just the number, warranted three awards," said Danchanko, interviewed a few weeks after the May 3 event. "It didn't seem fair that out of all these amazing projects, we'd only recognize one; so many of them were just outstanding."

Joan Godich, a nurse consultant with the hospital's Infection Prevention & Control (IPaC) unit, won the top quality improvement award for a team project on preventing septic arthritis after intra-articular joint infections. The result of infection by Staphylococcus aureus, this condition can cause serious damage to the treated joint.

When three such cases surfaced at the Physical Medicine and Rehabilitation unit in 2016, without serious harm to patients, Godich joined efforts to avert a worse scenario. Patient Safety convened a multi-disciplinary team, which interviewed staff members and took an in-depth look at all treatment steps.



Joan Godich, a nurse consultant with the hospital's Infection Prevention & Control unit, won the first-place award for quality improvement with her team's project on preventing septic arthritis. (Photo by John Fadoju)

The IPaC team led efforts to retool practices, from using multidose vials for only one patient to setting up a special medication room, away from bustling hallways. With this new system in place, infections halted.

"It was truly a collaborative effort," said Godich in an interview, giving credit to the clinic's staff, from physicians to nurses.

The second-place QI winner, Navy Lt. (Dr.) Sara Robinson, probed ways to cut costs by reducing unnecessary medical tests. Finishing third in this category, Navy Lt. Junior Grade Lauren Cebulski documented how involving patients and their families can cut medication errors on a pediatric inpatient unit.

Even older children and adolescents can benefit from playing a role in checking their medications, suggested Cebulski in an interview. Many such patients, she noted, suffer from chronic diseases that they may have to manage for the rest of their lives.

"It helps them feel empowered and part of the process, and have a chance to take ownership of their diagnosis," Cebulski said.

See POSTER WEEK, page 5



### **POSTER WEEK, from page 4**

### Singular cases chronicled

This year's case report awardees arguably made up in originality for any downturn in the number of abstracts.

Winning for fellow and staff case reports, Army Capt. (Dr.) Anna Isfort brought a mix of genetics and medical detective work to her project. One day, an 8-year-old boy walked into her clinic with severely short stature, hypermobile joints and lax skin. Isfort, a pediatric endocrine fellow, at first was stumped for a diagnosis.

Then Isfort's coauthors, Dr. Jeffrey Baron and Dr. Youn Hee Jee of the National Institute of Child Health and Development, ran some genetic tests on the boy and his family. Amid the lab work, the team homed in on FBN1, a gene that directs formation of fibrillin-1. This large protein helps form the microfibrils that allows skin, ligaments and blood vessels to stretch and lends strength to bone and tissues around the eyes, muscles and nerves.

Mutations in FBN1 can affect stature, joint function and skin elasticity, Isfort knew. The gene is linked to acromicric dysplasia, which entails extremely short stature, stiff joints and unusual facial features. Other changes in the gene result in Marfan syndrome, which involves unusual tallness, hypermobile joints, loose skin, and abnormalities of the heart and eyes.



Army Capt. Anna Isfort explains the unusual case that led her and colleagues to identify a new form of acromicric dysplasia, a rare genetic disease that stunts a child's growth. Isfort won the case report award for fellows and staff on May 3 during the Poster Display Week competition. (Photos by Paula Amann)



As colleagues and judges look on, Army Capt. Elizabeth Cleveland describes the case that inspired a new treatment for alopecia universalis, a rare form of hair loss. Her case report won the award for interns and residents at the Poster Week competitions on May 3.

Yet, the genetic tests revealed that the boy differed from four close family members in his FBN1 structure. The upshot: Isfort and her team may have discovered a new form of acromicric dysplasia.

"This case broadens the spectrum of phenotypes [observable traits] associated with FBN1," Isfort said.

In the case report contest for interns and residents, Army Capt. Elizabeth Cleveland, a transitional year intern, won for her project on treating a patient with a rare form of hair loss, alopecia universalis. Previously stationed outdoors, this active duty service member was suffering from blurred vision.

The cause was simple: He lacked eyebrows to catch the sweat pouring down his brow in desert heat. Yet, despite many attempts at traditional treatment, the problems persisted.

Then the Dermatology Clinic at Walter Reed Bethesda prescribed oral tofacitinib. This drug inhibits an intracellular pathway involving the Janus Kinase (JAK), a protein that helps direct growth and development, in tandem with Signal Transducer and Activator of Transcription (STAT) proteins. After 10 months of treatment, the man had regained 90 percent of his hair, she reported.

See POSTER WEEK, page 6

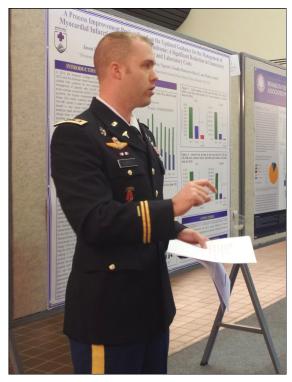


### POSTER WEEK, from page 5

However, the drug can weaken immune function, so the patient gets frequent lab tests and is monitored closely.

Cleveland is exploring use of a different JAK/STAT inhibitor, ruxolitinib, as a topical alternative with potentially fewer risks at a cheaper price, as tofacitinib costs thousands of dollars a year.

Next for Cleveland: "more research to deliver the lowest dose that's effective for the lowest cost."



Army Maj. Jason Reese, a cardiovascular medicine fellow, details an effort to reduce needless cardiac tests that is saving money and staff time at Walter Reed Bethesda. Reese won this year's evidence-based practice award. (Photo by Paula Amann)

### Evidence for better care – and cost savings

This year's winner for evidence-based practice, Army Maj. Jason M. Reese, designed a project that strengthens cardiac care while cutting needless tests and costs.

The 2014 guidelines from the American College of Cardiology and American Heart Association urge use of cardiac troponins as the best biomarkers for acute coronary syndrome. The American Board of Internal Medicine's Choosing Wisely campaign discourages tests of creatine kinase (CK) and another kinase, CK-MB, in such cases.

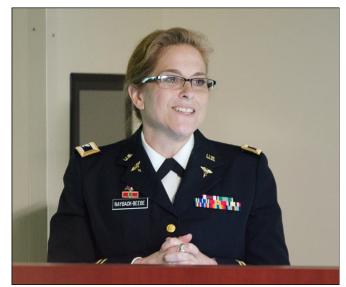
Reese, a cardiovascular medicine fellow, led efforts to reduce their routine use for assessing acute coronary care syndrome.

"Collaboration between the laboratory and the clinic can save time and money," said Reese at Research Symposium I on May 9.

During the project's first year, the hospital saved \$61,883 and in the second, a projected \$75,000 or more. Over three years, Reese said, the changes could save as much as \$213,412 in costs – plus more than 2,100 hours of laboratory staff time.

In her closing remarks as master of ceremonies for Research Symposium I, Army Col. Ann Nayback-Beebe underscored the impact of projects like this and those of the other award winners.

"This work has the power to help translate the findings from research into changes at the bedside," Nayback-Beebe said. "With these efforts, we can improve the quality of care provided to our beneficiaries with an eye on cost savings for the organization."

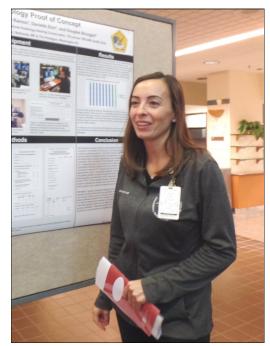


The master of ceremonies for Research Symposium I, Army Col. Ann Nayback-Beebe, sums up the day's presentations on May 9. See also story on page 9 for details of her own research. (Photo by John Fadoju)



## Florentino awards put patients at the heart of care

by Paula Amann



Army Capt. Georgina Blasco vies for the Paul Florentino Patient— and Family-Centered Care Award on May 4. An audiologist with the National Military Audiology and Speech Center, Blasco won the first-place award for her tele-audiology project. (Photos by Paula Amann)

Research and Innovation Month drew some fresh faces and ideas about patient care this year. Joining events showcasing research, case reports, evidence-based practice and quality improvement was the contest for the Paul Florentino Patient- and Family-Centered Care Award.

The 10 finalists at the May 4 event ranged from doctors and nurses to professionals in allied fields such as social work and public health. Project topics were as varied – from building communication skills among nurses around palliative care to preventing cardiovascular disease through healthy cooking.

Contestants described the work captured on their posters before some 50 peers, patients and judges. Audience members later mingled at a catered reception, courtesy of the Oak Leaf Club.

Army Capt. Georgina Blasco, an audiologist with the National Military Audiology and Speech Center, won the first-place award for her project on tele-audiology. She and colleagues got a tele-medicine cart and devised a program to help patients get remote care for hearing problems by trained audiologists. The system aims to serve people who may live far from military treatment facilities with specialty care and are coping with multiple health care needs.

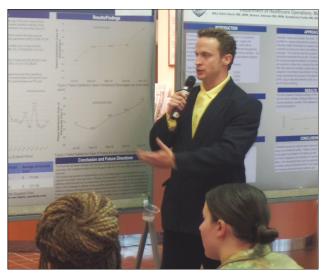
"A lot of these patients have TBI [traumatic brain injury] and PTSD [post-traumatic stress disorder], so they're dealing with a lot more than hearing loss," said Blasco in her talk at the Florentino event.

Tele-audiology allows people to get up to 10 different services from hearing evaluations to tinnitus management without leaving their desk. So far, the new system has served over 600 patients with an estimated cost savings of more than \$100,000, Blasco noted.

"The patients absolutely love the care," said Blasco, pointing to average satisfaction ratings of 4.96 out of a potential 5, with 5 as the highest rating.

In second place was Travis Combest, an exercise therapist, for spotlighting how three-day phone reminders cut appointment no-shows and boosted patient satisfaction at the Outpatient Nutrition Clinic. The system, developed with Army Capt. Paul Rosbrook, the clinic's chief, drove down no-show rates by some 40 percent and yielded estimated savings of \$40,850 a year, Combest said.

### See HEART, page 8



Travis Combest, an exercise therapist, partnered with Army Capt. Paul Rosbrook, the chief of the Outpatient Nutrition Clinic, to reduce appointment no-shows and increase patient satisfaction at the clinic. Their project won second place at the Florentino awards on May 4.



### **HEART**, from page 7

Laura Wandner, a psychologist in the Pain Clinic at Walter Reed Bethesda, won third prize for a project to prescreen patients before implantation of a spinal cord stimulator.

The Florentino award honors Dr. Paul F. Florentino (1955-2011), whose career propelled him from work as an Air

Force flight surgeon to deputy commander of medical services at the former National Naval Medical Center. In this role, he helped guide the integration of the naval facility with Walter Reed Army Medical Center.

Florentino also championed patient- and family-centered health care, noted Lina Kubli, awards emcee, program chairperson and past chair of the Patient- and Family-Centered Care Steering Committee. Formerly a research audiologist with Walter Reed Bethesda, Kubli is now a scientific program manager at the U.S. Department of Veterans Affairs and a VA liaison to the Florentino awards committee.

"I think we all want that human by Paula Amann) connection, whether we have served in the military or not," Kubli said in her remarks on May 4.

Kubli chaired the committee planning the event until August 2016. Others on the committee were Dr. Kameha Bell, Dr. Thomas Fitzpatrick, Michelle Mason-Coles, Michael Joseph, Victor Mosley, Lt. Cmdr. Bryan Pyle, Terry Sellars and Sharon Stentz. Dr. Marc Williams served as consultant from Army Public Health Command.

Ranking the projects were five judges ranging from neurologist and patient advocate, Dr. Fred Foote, to Sgt. Jonathan Harmon, a combat veteran who lost both his legs and is now a liaison to other wounded vets.

Human protections expert, Hope Hougzu He, from the

Agency for Healthcare Research and Quality and retired Air Force Master Sgt. Ricardo Gonzalez, now administrative officer for the Rehabilitation Research and Development Service of the VA also served as judges.

Rounding out the panel was retired Air Force Col. Dr. David Welling, professor of surgery at Uniformed Services University of the Health Sciences and a former chief consultant to the Air Force Surgeon General on colorectal surgery.

Keynote speaker Claudia Avila brought a personal view of patient- and family-centered care to the Florentino event as the wife and caregiver of Army Capt. Luis Avila. On a 2011 deployment to Afghanistan, the speaker's husband lost a

leg, broke his spine, had two heart attacks and suffered severe traumatic brain injury – all of which left him in a temporary coma. He is now regaining sight, speech, some movement and a life, said his wife, with help from her and his health care providers.

"Behind every wounded warrior, there's a wounded family," Avila said in her remarks. By empowering those families, she added, you empower wounded warriors. ■



Lina Kubli, emcee for the Paul Florentino Awards and its program chairperson, speaks at the awards event May 4. (Photo by Paula Amann)

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# **PowerPoints and partnerships** Spring summit informs, links military medical researchers

### by Paula Amann

A select group gathered on May 24 at Walter Reed Bethesda for the Spring Research Summit. This final event of Research and Innovation Month was as much about "scientific matchmaking" as about sharing topline information.

Diana Luan, the new science director at the Uniformed Services University of the Health Sciences, stressed that first objective in her remarks there.

"I'm here to look for collaborators and partners," she told the audience in Memorial Auditorium at Walter Reed National Military Medical

Center. "We are driven by outcomes, and we've found health outcomes research is an unmet need."

The 14 research areas explored in May's summit ran the gamut from health policy to medical pedagogy, and

osseointegration to prediabetes prevention and vision care.

Christopher Dearth, facility research director for the Extremity Trauma and Amputation Center of Excellence, also came seeking partners. The center has the job of crafting a plan to mitigate, treat and rehabilitate extremity injuries and amputations.

Dearth's staff does research with three goals in mind: saving injured extremities, avoiding amputations, and preserving and restoring function in injured extremities.

Looking forward, Dearth sees the center not only fine-tuning orthotics and prosthetics for optimal function



Christopher Dearth, facility research director frontiers of trauma surgery, Navy for the Extremity Trauma and Amputation Center of Excellence, presents his center's research priorities at the Spring Research

at Walter Reed Bethesda and a Summit on May 24. (Photos by John Fadoju) surgery professor at the Uniformed Services University of the Health Sciences, Forsberg is one of two active duty surgeons in the U.S. military to have performed osseointegration. This innovative

direct attachment of a prosthesis.

operation joins human bone to a synthetic implant for

an orthopedic oncologist at the

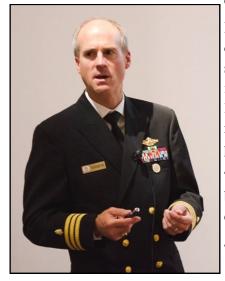
Cmdr. Jonathan Forsberg. On staff

Forsberg sketched three main areas of osseointegration research: optimizing skin-implant junctions, minimizing infection and controlling prosthetics. Investigators have conducted early research to refine and test the surgical procedure in pigs.

"It is a big implant in a relatively small bone," said Forsberg, citing one of the challenges of the procedure under study.

Turning from trauma to long-term health, another summit speaker, Marina Vernalis, described research on the pervasive problem of prediabetes. This condition is a precursor of diabetes,

See PARTNERSHIPS, page 10



Navy Cmdr. Jonathan Forsberg, an orthopedic oncologist at Walter Reed Bethesda and a surgery professor at the Uniformed Services University of the Health Sciences, shares the latest research on osseointegration at the summit.

### PARTNERSHIPS, from page 9

itself a risk factor for cardiovascular disease, the top cause of death and disability in Westernized countries.

New research, said Vernalis, standing in for Mariam Kashani, associate medical director of the Integrative Cardiac Health Project, is bringing fresh insights on countering prediabetes.

Stress management and better sleep, stressed Vernalis, are as critical to reversing the condition as proper diet and exercise

"The lifestyle management changes were particularly important as patients did not lose significant weight," Vernalis said of her team's findings.

A couple of speakers reminded the summit audience that sometimes research delivers a ringing "no" to a hypothesis. This can prove as useful for medical treatment and policy as a resounding "yes."

Army Col. Ann Nayback-Beebe, a senior scientist with the Center for Nursing Science and Clinical Inquiry and the former deputy chief of the Department of Research Programs, shared an example of such research.

Exploring alternatives to opioids for pain, she looked at the impact of MC5-A Scrambler therapy on chronic neuropathic extremity pain.

Nayback-Beebe's double-blind, randomized, controlled study of Scrambler Therapy versus sham treatment showed no improvement with Scrambler – and an actual increase in participant use of pain medications.

Given these results, her research could help health care leaders avoid investing in costly, time-consuming therapies that yield few benefits.

Similarly, Navy Cmdr. William
Danchanko, chief of the Center for Nursing
Science and Clinical Inquiry, has been
examining the health impact of embedded
shrapnel.

Such fragments can include toxic lead and carcinogenic nickel and cobalt, along with radioactive depleted uranium.

Danchanko set out to determine if the shrapnel caused long-term harm within the body. The results revealed no such harm.

Twenty years out from known exposure to depleted uranium, for instance, service members showed no identifiable health effects. Studies like Danchanko's may help guide medical decisions about whether or not to remove shrapnel.

Another researcher at the summit, retired Army Col. Dr. Virginia Randall is probing questions of medical pedagogy. Her qualitative study focused on the formative ideas, or "threshold concepts," that turn medical students into physicians.

A threshold concept transforms people, stays with them forever, makes sense of other ideas and stirs up difficult feelings, such as depression and anxiety.

One such concept that emerges from Randall's analysis of reflective essays from pediatric clerks is "It's about the patient."

In the early stages of their medical training, "Students sometimes think it's about how smart they are, but they learn it's about the patient," Randall said.

If an overall threshold concept emerged from this year's

summit, it might have been this: Collaboration drives research success in the early 21st century.

"The days of individual investigators working in silos are over," noted Dearth in his remarks.

The summit formula seems to have worked for Dearth and his colleagues, as they track outcome measures on patients with limb trauma.

"For us, it already paid dividends, because we met two potential partners," Dearth said in a phone interview in early June. "There's so much groundbreaking, cutting-edge research that it's sometimes hard to know what's going on, so having a dedicated event on this is really helpful."



Retired Army Col. Dr. Virginia Randall is exploring how medical students learn, through the lens of "threshold concepts." These lifechanging insights, she said, can stir anxiety during training, (Photo by John Fadoju)



## Aware for All sees surge in number of groups taking part

### by Paula Amann



From left, Army Sgt. Alisha Kohler of the Department of Research Programs talks with Jon Peck of the Warrior Canine Connection, as Wilma (a service dog trainee), Jenna Hagin, Saba Khairullah and Cheryl Hoehner of the Consortium for Health and Military Performance look on. The consortium was among 29 research groups that took part in Aware for All on May 16. (Photo by Paula Amann)

The lobby of America Building and its adjoining wings were thick with display tables on May 16, as Walter Reed National Military Medical Center marked the 5th Annual Aware for All.

This observance honors and recruits participants for medical research conducted by investigators at Walter Reed Bethesda and their research collaborators. Now in its fifth year, Aware for All drew 29 research teams, up by 24 percent from the 22 teams that took part last year.

The research groups represented ran the gamut from brain injury and breast cancer to heart health and rehabilitation. In the opening program, a keynote speaker with a family tree rich in military service put the value of such research in sharp relief.

Retired Air Force Lt. Col. James M. Beebe traced his own debt to military medicine back four generations. A great-great-grandfather took bullets from a sniper at the Civil War battle of Gettysburg, Pennsylvania; and was treated by surgeons.

A grandfather served in World War II and Beebe's father in both Korea and Vietnam. Both men benefited from military medicine and military medical research

His grandfather's health was closely tracked after he served three years as a prisoner of war in Corregidor. Meanwhile, his father enrolled in a

cancer study after coping with the aftereffects of Agent Orange while serving in Vietnam.

"War is the dark side of humanity; military medicine is the light," Beebe said, pointing to current tourniquets that have saved countless lives in the Iraq and Afghan theaters.

Aware for All also featured a welcome by Lisa Thompson, supervisory medical education specialist; opening remarks by Navy Cmdr. Robert A. Liotta, director of Education, Training and Research; closing remarks by Army Col. Peter J. Weina, chief of the Department of Research Programs;

### See AWARE, page 12



Retired Air Force Lt. Col. James M. Beebe talks about the four generations of men in his family who benefited from military medicine and medical research at Aware for All's opening program. (Photo by Bonnie Bloomquist)



### AWARE, from page 11

and the singing of the National Anthem by Navy Petty Officer 2nd Class Rhesa Cantu.

One third of all medical research done within the U.S. Department of Defense takes place at Walter Reed Bethesda, with some 600 publications a year flowing from the hospital, Liotta said.

Patients who take part in these studies, he noted, have a bill of rights that includes knowing the risks and benefits of a study, as well as the right to quit their involvement at any time.



Navy Petty Officer 2nd Class Rhesa Cantu fills the lobby of the America Building with sound, as she sings "The Star-Spangled Banner" during the opening program of Aware for All on May 16. (Photo by Paula Amann)

In his own remarks, Weina cited the "remarkable advancement" in the treatment of diseases such as AIDS, thanks in part to military medical research.

"When it first appeared, a diagnosis of HIV was a death sentence," Weina said. "Survivors now deal with diabetes [and] geriatric complaints."

In answer to an emailed question about response rates, most liaisons to participating research teams voiced overall satisfaction with the event. (Organizers assign tables on a first-come, first-served basis.)

Responding for the Consortium for Health and Military Performance, staffer Lorne Merriett reported results to date: 85 visitors, 18 people who signed up for a study, and two who have already enrolled in one.

Jody Bindeman, a nurse specialist with Cardiology Services at Walter Reed Bethesda, said her table display attracted 20-25 visitors. She described this as "a pretty good return for the effort considering our remote position as second to last table on the 'B' hallway."

As of June 12, Bindeman reported, of the eight people who signed up for a study, three have already enrolled, two are pending and three did not meet criteria for participation.

At the Immunization Healthcare Branch of the Defense Health Agency, Connie Lohsl, a research nurse, reported at least 35 people had visited her table. Of the five who signed the guest sheet, four had enrolled in a study, she said.

Meanwhile, the table for the Extremity Trauma and Amputation Center of Excellence saw about 25 people drop by, said Elizabeth Husson, a research program manager with the center.

"While none of them formally enrolled in a research study as a result of the Aware for All event, we did consider this a successful engagement as many were interested in the work that we do and we were able to spread the word about our various studies," Husson reported in an email.



Navy Cmdr. Robert Liotta, director of Education, Training and Research, joins Army Col. Peter Weina in cutting the cake at the closing program of Aware for All. (Photo by Bonnie Bloomquist.)



### SCIENCE, from page 1

He pointed to such examples as the Human Genome Project, the use of precision medicine to treat cancer, and the widespread use of laparoscopic surgery. In fact, these advances underpin several of the prize-winning research projects at this year's symposia.



Maj. Kristen Zeligs, a gynecological oncology fellow, won a Robert A. Phillips Award for showing that NEO-21, a new antibody, can target cancer cells in the laboratory. Here she shares her research on May 9 at Research Symposium I (Photos by John Fadoju)

Adding to knowledge of precision medicine, Zeligs tested the laboratory use of NEO-201, a new monoclonal (single-cloned) antibody created by Precision Biologics in Rockville, Maryland.

The second-year gynecological oncology fellow confirmed that this antibody had the "unique ability to be tumor specific" – in effect, binding to cancer cells and not to healthy ones.

Findings like these are helping to drive NEO-201 toward clinical trials for human use as early as next fall, depending on approval of a new drug application to the U.S. Food and Drug Administration, said Dr. Philip Arlen, the company's CEO, in a phone interview.

Driving advances in surgical practices was Ashford laboratory winner Pavey, who tested three new drugs on rats to gauge their efficacy for blocking heterotopic ossification. This condition, the formation of unwanted bone within soft tissue after trauma, has confounded the medical field.

Pavey discovered all three drugs – Palovarotene, intrawound Vancomycin powder and Rapamycin – reduced the volume of abnormal bone in the rats. Given results, this orthopedist has proposed the use of topical antibiotics for open fractures and amputations on the battlefield or at the first point of combat casualty care.

On the clinical side of surgery, the question of how long to wait after arthroscopic hip surgery before driving inspired another Ashford-winning project. In preparing for this research, winner Balazs, also an orthopedic surgeon, learned that 68 percent of surgeons are uncomfortable talking about driving with patients and 76 percent have no policy on how long to wait after surgery

"Patients are left to drift when it comes to going back to driving," lamented Balazs in his talk at Research Symposium II on May 10.

In response, he designed a study to look at measures of driving safety such as brake reaction time. The time when it's safe to return to the wheel, it turns out, depends on which side gets operated on.

Patients on the mend from left hip arthroscopy brake normally, Balazs found. However, patients with the

### See SCIENCE, page 14



Navy Lt. Cmdr. George Balazs, an orthopedic surgeon, won a Bailey K. Ashford Award for his study on when it is safe for patients to drive after arthroscopic hip surgery. Here Balazs presents his findings at Research Symposium II on May 10.



### SCIENCE, from page 13



Lt. Col. E. Matthew Ritter garnered a clinical award in the Robert A. Phillips competition last month. Here, on May 10 at Research Symposium II, Ritter describes the simulation curriculum he developed to train future surgeons in endoscopy. (Photos by John Fadoju)

right hip procedure should wait four weeks to ensure normal braking.

"We're hoping these data will guide our patients when they ask that inevitable question: When can I go back to driving?" Balazs said.

As a teaching hospital, Walter Reed Bethesda not only serves patients, but also trains physicians. To that end, Phillips winner Ritter turned his research skills to the question of how best to teach residents to carry out a colonoscopy and similar procedures, known collectively as endoscopy.

His new curriculum melds the ideas of mastery learning, such as baseline assessment and mastery of discrete educational units, with simulation tools.

Step by step, residents build dexterity by practicing with medical models that resemble the patients they will treat in the operating room.

Their practice in the Simulation Laboratory, said Ritter, "frees up cognitive load to focus on other things in the clinical environment" such as positioning the patient.

Ritter is confident that his curriculum builds the right skills, as his research participants skyrocketed from an 18 percent pass rate on the pre-training assessment to 100 percent on the post-training assessment.

"We've shown we can train people to pass this really important test," Ritter said. The next step, he added is to show how much "experience" the training adds to a new surgeon's skills.

From teaching surgeons to finding potential cancer cures to blocking heterotopic ossification, the researchers who competed at this year's symposia are expanding the boundaries of medical science.

Among the Symposia's closing speakers was Yvonne Maddox, the vice president for research at the Uniformed Services University of the Health Sciences. Maddox touted her institution's partnerships with Walter Reed Bethesda and the National Institutes of Health, where she previously served in several key leadership roles.

She also reminded the audience in Memorial Auditorium of the ultimate aim of medical research.

"Research is the window into giving our patients the very best care possible," Maddox said. ■



Army Col. Peter J. Weina, the chief of the Department of Research Programs, served as the master of ceremonies for Research Symposium II. A long-time researcher himself, Weina paid tribute to the time, hard work, and commitment of those competing for the Ashford and Phillips awards – on top of full-time jobs.



# DEPARTMENT DOWNLOAD News from the Department of Research Programs

At May's monthly meeting of the Department of Research Programs, Research and Innovation Month took center stage (see stories starting on cover and continuing on page 4).

Meanwhile, Army Col. Peter J. Weina, the department chief, pointed to recent statistics on the processing of research protocols. Two years ago, in June 2014, new protocols used to take 270 days to process. Now it takes about 90 days, as the backlog for protocols is progressively shrinking.

Staff members got a chance to meet new hire, **Stephanie Marquez**, who began work at in the department early May as a research protocol specialist. Since then, two others have joined the staff: **Svetlana Smith**, a technology transfer specialist, and **Chia Wei Tsai**, a research chemist. Look for pictures and bios in next month's newsletter.

The department is helping to put a policy together for the command on people who are not enrolled in the Defense Enrollment Eligibility Enrollment System, or DEERS. DEERS is a system that, among other things, documents whether a person is eligible to receive care at a military treatment facility.

Active Duty military members, their dependents, retirees and their family members, as well as Secretarial Designees are eligible to receive care at a military treatment facility, and are eligible to participate in research studies conducted at Walter Reed National Military Medical Center.

The department's dashboard is being pushed out to the hospital's unit chiefs, so they can see their protocols. It will tell them how many protocols they have and who verified the study.

If questions of ethics surface during research at Walter Reed Bethesda, staff members can reach out to Weina, who is the research integrity officer for the hospital.

- Notes on May staff meeting courtesy of Patricia Titi

### TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

- Collaborative Institutional Training Initiative (CITI)
- Minimum Educational Requirement Framework (MERF)

Arrange training for your department or join our monthly classes. We have only eight spaces per class, so sign up today!

### Your Monthly Class

### Find it in Heroes Building (Building 5), fourth floor:

- July 10, 2 p.m., Computer Classroom 1 (Room 4010)
- Aug. 14, 2 p.m., Computer Classroom 1 (Room 4010)
- Sept. 13, 3 p.m., Computer Classroom 4 (Room 4031)

Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.

# You belong in the CITI. Start training today!





### RECENT PUBLICATIONS

### **Courtesy of Darnall Medical Library**

Find articles by authors at Walter Reed Bethesda in bold.

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See PUBLICATIONS, page 17



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### RESEARCH POLICY RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked web sites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the Defense Department does not exercise any editorial control over the information you may find at these locations.

### • Belmont Report

The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.

### Comparison of FDA and HHS Regulations

The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.



### **RESEARCH POLICY RESOURCES, from page 17**

#### • The President's Council on Bioethics

This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.

#### Clinical Trials.gov

Clinical Trails is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.

### • HHS Office for Human Research Protections

HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.

### • HHS Office of Civil Rights

HHC Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).

#### MedlinePlus

MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.

### • Office for Human Research Protections (OHRP)

OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.

### • Federal Policy for the Protection of Human Subjects ('Common Rule')

HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.

#### Protocol Review

HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.

#### • Informed Consent

HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to documentation.

### • Vulnerable Populations

HHS provides guidance for populations including prisoners, children, and HIV human subjects.

### Reporting Problems to the FDA

- Reporting Complaints Related to FDA-Regulated Clinical Trials
- Mandatory IRB Reporting: FDA Contacts
- Clinical Trial Forms •

# DARNALL MEDICAL LIBRARY Research and Scholarly Communication Support

Sarah Cantrell, Michele Mason-Coles, and Lyubov Tmanova, librarians, offer research support to Walter Reed Bethesda's biomedical community They lead research-oriented classes on a quarterly basis. Individual and group consultations are available upon request.

### Research and Scholarly Communication Classes • Building 5, Room 4011

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### Walter Reed National Military Medical Center Department of Research Programs



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